



BRITISH AMERICAN  
TOBACCO

A FOCUS ON HARM REDUCTION

# Why it matters

SUSTAINABILITY FOCUS REPORT 2013:  
How we address the public health impact of our products



A nicotine molecule

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# Our Chief Executive on why it matters





## Because it's crucial to the future of our business.

### Surely tobacco harm reduction should just be about getting people to quit smoking?

The only way to be certain of avoiding the serious health risks associated with smoking is not to smoke at all. However, despite increasingly strict tobacco control policies, many people continue to smoke. And the World Health Organisation estimates that many more will do so in the future<sup>1</sup>. So realistically the 'quit or die' approach to reducing the public health impact of smoking simply isn't enough.

For adults that choose to continue to smoke, tobacco harm reduction takes a pragmatic approach by offering them the choice of less risky tobacco and nicotine alternatives.

### OK, but can a tobacco company really be serious about harm reduction?

We understand that people will be sceptical about our motivations and how seriously we take this. As well as the moral imperative, it makes commercial sense for us to have a sustainable portfolio of products. Clearly, less risky tobacco and nicotine products *must* form part of that portfolio. And yes, we most definitely have a responsibility to work to reduce the risks of our products. Harm reduction is a crucial part of our future, with huge potential for business growth, while also benefiting public health.

This is not a new area; harm reduction has been a strategic priority for a long time. In fact, it's so important that we have two Management Board positions dedicated to this area – Dr David O'Reilly as Group Scientific Director and Des Naughton as Managing Director of Next Generation Products. And earlier this year, we welcomed a new independent Non-Executive Director, Dr Richard Tubb, to our Board of Directors. Dr Tubb is a leading public health figure actively involved in the science and policy development of tobacco harm reduction and alternative nicotine products.

These positions put science and alternative nicotine products at the core of our strategy, and further demonstrate our commitment to our consumers and shareholders.

### What areas are you concentrating on?

Our approach to harm reduction has two distinct areas: nicotine-based alternatives and reduced-risk tobacco products.

In the nicotine category, we have established a stand-alone business solely dedicated to this area. This brings together our existing Nicoventures business with CN Creative, the e-cigarette company we acquired at the end of last year, into a single business which will continue to operate under the Nicoventures name.

This business has already launched its first e-cigarette in the UK, which will be expanded into further markets in the coming year. And, as well as e-cigarettes, it's also developing other innovative nicotine inhalation devices. These products represent the first step towards creating a portfolio of nicotine alternatives, to realise the long-term potential of our harm reduction approach and a sustainable future growth for our business.

Our core business continues to be in tobacco and in this area we continue to focus on scientific research and clinical studies into reduced-risk tobacco products.

### So why do you have a separate business for nicotine products?

The rationale for Nicoventures being separate is to ensure focus. We are determined to create a nicotine business with global scale and reach and we want to ensure the management of it is not distracted with competing demands from the tobacco side of our business.

### How do we know we can trust you and have faith in your less risky products?

We know there's still widespread mistrust of the tobacco industry. That's why it's so important that the information consumers get about less risky products is based on robust science. We're working hard at re-building trust through open and frank communication with society and our consumers, as well as transparency about our scientific research. It may take many more years to do this, but we're in this for the long haul and I think there's a lot to be optimistic about in the future.

*Nicandro Durante*

Nicandro Durante, Chief Executive, November 2013

<sup>1</sup> Foreword by the Director-General of the World Health Organisation to *The Tobacco Atlas*, Fourth Ed. Eriksen M, Mackay J, and Ross H. American Cancer Society, 2012.

# Exploding the myths...

▶ **FACT**  
Scientists widely agree that it's not nicotine but in fact the toxicants in tobacco and tobacco smoke that cause the overwhelming majority of smoking-related diseases.

▶ **FACT**  
The World Health Organisation's International Agency for Research on Cancer has not identified nicotine as a cause of cancer<sup>1</sup>.

“  
Nicotine itself is not especially hazardous... if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved.

The Tobacco Advisory Group of the UK Royal College of Physicians<sup>2</sup>

CN1C=NC2=C1C=CC2

## Focusing on the facts

▶ **FACT**  
Nicotine is not added to cigarettes, it occurs naturally in the tobacco leaf and is also found, albeit at significantly lower levels, in other plants, such as tomatoes, potatoes and aubergines (eggplant).

“  
Nicotine inhaled from smoking tobacco is highly addictive. But it is primarily the toxins and carcinogens in tobacco smoke – not the nicotine – that cause illness and death.

UK National Institute for Health and Care Excellence (NICE)<sup>3</sup>

- <sup>1</sup> *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Tobacco Smoke and Involuntary Smoking*, International Agency for Research on Cancer, Volume 83, 2004.
- <sup>2</sup> *Harm reduction in nicotine addiction*, a report by the Tobacco Advisory Group of the UK Royal College of Physicians, 2007.
- <sup>3</sup> *Tobacco harm reduction approaches to smoking*, NICE public health guidance 45, 2013.

# At the **core** of our business strategy

## Our approach to harm reduction

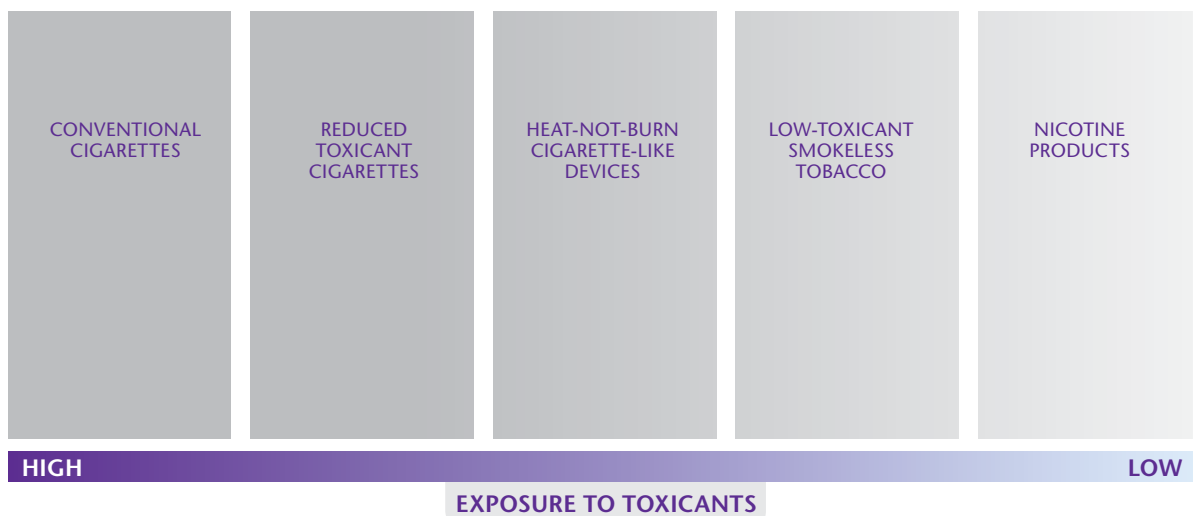
It's simple; we want to reduce the public health impact of our products. So, harm reduction continues to be at the core of our business strategy. But as consumer preferences vary widely, there's no one 'Holy Grail' product. We're working hard at making a range of less risky products available by focusing on two key areas:

- Developing nicotine-based alternatives, including e-cigarettes and other inhaled nicotine devices; and
- Scientific research into reduced-risk tobacco products, including reduced toxicant cigarettes and innovative next generation tobacco products.

We're seeking widespread support for tobacco harm reduction through our engagement and work with scientists and public health professionals. We're also asking for regulatory changes that will support the commercialisation of reduced-risk, scientifically assessed products.

### The risk spectrum

Different products are shown along our risk spectrum, based on their toxicant levels. Conventional cigarettes carry the highest risk, while appropriately regulated nicotine products, which offer nicotine without tobacco or smoke toxicants, are substantially less risky.



## Weighing up the evidence

It has been determined in public health reports over many years that exposure to nicotine in itself is not a significant risk factor in the development of smoking-related diseases.

The UK Royal College of Physicians states that "medicinal nicotine is a very safe drug"<sup>1</sup>. And the UK Medicines and Healthcare products Regulatory Agency states that "there is a large body of evidence that medicinal nicotine (in currently licensed forms) is not a significant risk factor for cardiovascular events, and does not cause cancer or respiratory disease"<sup>2</sup>.

## A pragmatic approach

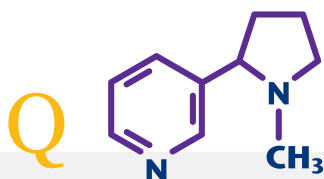
Tobacco control policy around the world focuses on urging people not to start smoking, or to quit. Yet many adults continue to smoke, and the World Health Organisation estimates that, as the global population increases, so too will the number of smokers<sup>3</sup>. If this is the case, then the pragmatic approach is to offer them less risky alternatives.

1 *Harm reduction in nicotine addiction*, a report by the Tobacco Advisory Group of the UK Royal College of Physicians, 2007.

2 *The use of nicotine replacement therapy to reduce harm in smokers*, a public assessment report by the UK Medicines and Healthcare products Regulatory Agency, 2010.

3 Foreword by the Director-General of the World Health Organisation to *The Tobacco Atlas*, Fourth Ed. Eriksen M, Mackay J, and Ross H. American Cancer Society, 2012.

# Innovative nicotine products



Aren't nicotine products just as bad for you as cigarettes?

A

"No. That's one of the great misconceptions out there. Although nicotine is derived from tobacco, pure nicotine products, including e-cigarettes, do not expose users to the smoke toxicants produced from burning tobacco – which makes them substantially less risky.

"It's not just us saying that – the scientific community widely agrees that it is the toxicants in tobacco and tobacco smoke, rather than the nicotine, that cause the overwhelming majority of smoking-related diseases.

"There's lots of independent information out there, which we refer to throughout this report so you can judge for yourself."

Q

So where do you see this category going?

A

"There's already a lot of consumer interest and early indications are that the nicotine category has huge potential for business growth. But it's still early days and I believe further development can make nicotine products even more appealing to consumers.

"As awareness and understanding of their harm reduction potential grows, I think innovative nicotine products, as an alternative to cigarettes, will become a key pillar of public health policy."

Q

nicoventures

So how does this fit into your strategy?

A

"For a long time, BAT has been committed to harm reduction and the alternative nicotine product category is a natural extension of this – especially as it provides a more immediate opportunity to bring less risky products to market.

"But this is a relatively new area and is very different from tobacco products – especially in terms of the marketplace and regulatory environment. So our Nicoventures business is focused exclusively on satisfying consumers with innovative nicotine-based alternatives to cigarettes.

"Nicoventures' strategy is to give smokers much of the experience they expect from a cigarette but without the serious health risk. We've recently launched our first e-cigarette brand, Vype, in the UK. But this is just the beginning. We are committed to an innovations pipeline that will build a portfolio of high-quality next generation nicotine products that will satisfy consumers and meet future regulatory requirements."

Q&A with Des Naughton  
Managing Director of Next Generation Products

## The potential of e-cigarettes for improving public health

E-cigarettes deliver nicotine without smoke toxicants. Consumer research suggests that, due to being closer to the experience of smoking tobacco, they are the first product with the potential to encourage meaningful numbers of smokers to reduce or stop smoking conventional cigarettes. They could therefore play a significant role in helping to reduce the public health impact of tobacco use.

We think that further product development can build on the success of e-cigarettes, achieving greater public health benefits and providing us with a commercial opportunity.

When manufactured to appropriate quality and safety standards, e-cigarettes are substantially less risky than smoking tobacco. However, no product is free from risk.

Nicotine is addictive and can be dangerous if ingested in concentrations much higher than found in cigarette smoke or e-cigarette vapour. Therefore, our e-cigarettes packs, inserts and e-liquid refills have appropriate warnings, are sold in child-proof containers, and are clearly labelled as being for those aged 18 and over. Our marketing of e-cigarettes is aimed at adult smokers only.

Questions are also asked about the possible long-term effects of inhaling substances found in e-liquids, such as glycerol and propylene glycol. Although these ingredients are commonly approved for use in food and medicines, we believe that more research is needed in relation to their inhalation and so we are planning our own studies in this area.

Certain members of the public health community are concerned that e-cigarettes could act as a 'gateway' into smoking, particularly for young people. So far there is little evidence to suggest this is the case. Studies in the UK and United States show that 0.5%<sup>1</sup> and 0.8%<sup>2</sup> of adults who had never smoked reported having ever tried an e-cigarette.

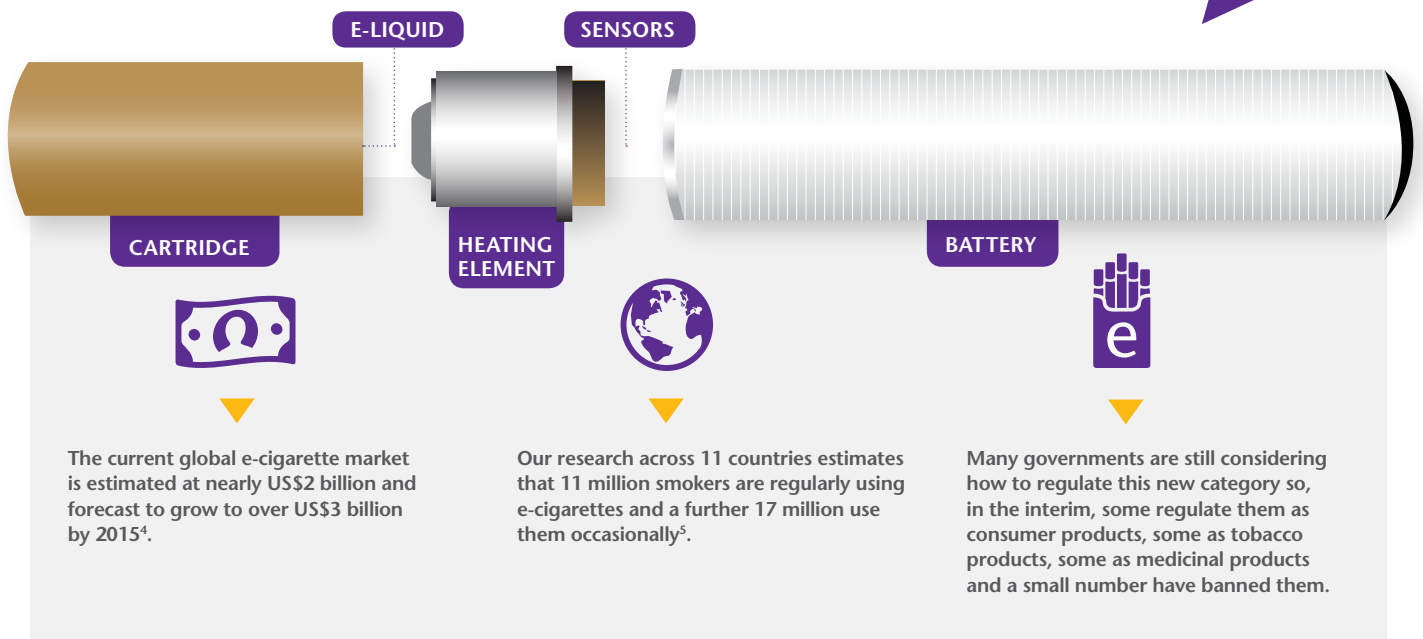
## Other nicotine inhalation products

As well as e-cigarettes, our Nicoventures business is also focusing on the development of other innovative nicotine inhalation devices. Most of the current nicotine inhalation products on the market are categorised as 'nicotine replacement therapy' (NRT) and sold as aids to help people quit smoking. But we think this approach positions smokers as patients. Research shows that smokers don't perceive themselves as having a disease and we don't think these NRT products meet their needs.

The UK Department of Health has expressed its interest in encouraging manufacturers "to develop new types of nicotine products that are more affordable and that have increased acceptability for use in the longer term"<sup>3</sup>.

We think we're up to meeting this challenge and so Nicoventures is working on bringing innovative inhaled nicotine products to market that appeal to smokers as people not patients.

A typical e-cigarette consists of three main components: a battery, a heating element and a cartridge containing water, nicotine and other ingredients, including glycerol or propylene glycol, known as 'e-liquid'. When a user inhales on the device, a sensor detects air flow and the e-liquid is heated so that it turns into vapour, which delivers nicotine to the user. What looks like exhaled smoke is largely odourless vapour.



1 *E-cigarettes: Prevalence and attitudes in Great Britain*, Dockrell M, Morrison R, Bauld L and McNeill A, Nicotine & Tobacco Research, July 2013.

2 *E-cigarette awareness, use, and harm perceptions in US adults*, Pearson JL, Richardson A, Niaura RS, Vallone DM and Abrams DB, American Journal of Public Health, September 2012.

3 *Healthy lives, healthy people: A tobacco control plan for England*, UK Department of Health, 2011.

4 Linarch Reports and Citi Research, May 2013.

5 Research commissioned by BAT and undertaken by Grail Research covering the USA, Mexico, UK, France, Germany, Poland, Spain, Italy, Russia, Japan and South Korea, February 2013.

Q



Do you think nicotine products should be regulated?

A

“Yes, we absolutely support regulation of nicotine products, including e-cigarettes. It needs to be recognised though that they contain no tobacco and are substantially less risky than cigarettes, so to regulate them in the same way would be inappropriate. To me, it goes without saying that different products should be regulated differently based on their respective risk profiles.

“So, given this, we want to see a regulatory approach that puts consumer safety and product quality first, while allowing the appropriate level of innovation, marketing and distribution freedoms so as not to hamper the growth of a product category that could help smokers to cut down or quit.”

Q



So how can you be sure your products meet quality and safety standards?

A

“We have a very strict approach to product stewardship and would never put any product on the market, regardless of the regulatory environment, without meeting our own high product safety and quality standards. This includes toxicological testing, using only pharmaceutical-grade nicotine in our e-liquid and compliance with all rules relevant to the manufacture, content and labelling.”



Q&A with Kingsley Wheaton  
Group Corporate and Regulatory Affairs Director

## Regulating nicotine products

We recommend the following regulatory environment for nicotine products and e-cigarettes:

- ▶ High quality and safety standards;
- ▶ A minimum age law of 18 for sales;
- ▶ Relevant consumer information on the risk profile;
- ▶ Wide retail and online availability;
- ▶ Appropriate marketing freedoms; and
- ▶ Flexibility to enable the swift introduction of new products.

“

If all the smokers in Britain stopped smoking cigarettes and started smoking e-cigarettes we would save 5 million deaths in people who are alive today. It’s a massive potential public health prize.

Professor John Britton, 2013<sup>1</sup>

<sup>1</sup> Professor John Britton, Chair of the UK Royal College of Physicians’ Tobacco Advisory Group and Professor of Epidemiology at the University of Nottingham in the UK, 2013.



# 'Safer' tobacco products: the research

## Scientific research

Globally, cigarettes are by far the most popular form of tobacco use – not only because of the way they offer nicotine (quickly and with control by the smoker) but also because of taste and the rituals surrounding smoking. Producing less risky products that smokers actually want to switch to is challenging.

Evidence tells us that certain low-toxicant smokeless tobacco products, such as Swedish-style 'snus', come with substantially lower risks than cigarette smoking. The wide use of snus among Swedish men is seen as an important reason why Sweden has the lowest rate of male smoking-related diseases of any comparable developed nation<sup>1</sup>. However, snus is currently banned from sale in some parts of the world and, outside of countries that have a history of using oral tobacco, smokers generally don't like using it in preference to cigarettes.

Yes, alternative nicotine products have great promise, but it's also really important to look for other ways of reducing the risks of conventional tobacco products.

### Reduced toxicant cigarettes

We've developed new technologies to reduce some of the toxicants in the smoke, which we're testing in prototype cigarettes. We're researching their potential to reduce exposure to toxicants and, ultimately, health risks.

A lot of this research is lab-based. It includes tests involving the development of *in vitro* models of disease and computational

toxicological models to determine which are the most important toxicants, and how much they would need to be reduced to lessen health risks. This research supports our approach, but the key evidence of the possible exposure and risk reduction comes from clinical studies of groups of smokers.

Our first clinical study of this kind showed that smokers who switched to the reduced toxicant prototype cigarettes had less exposure to certain smoke toxicants than people smoking conventional cigarettes.

This is a good first step. But we did not determine whether the reduced exposure will reduce risk. In 2012, we completed the clinical phase of a longer study to measure biomarkers of biological effect that could indicate changes in the body relating to diseases. Initial results of the study have been presented to the joint meeting of the US Food and Drug Administration's Risk Communication Advisory Committee and Tobacco Products Scientific Advisory Committee. We will be submitting the full findings to peer-reviewed journals at the end of 2013.

### Other innovative tobacco products

We are also exploring the development of other innovative tobacco products, such as 'heat-not-burn' cigarette-like devices. These gently heat the tobacco, instead of burning it, which potentially exposes users to lower levels of toxicants.

## Why is smoking so harmful?

- ▶ Conventional cigarettes are made up almost entirely of tobacco, which when burned produces smoke.
- ▶ Exposure to toxicants, by inhaling the smoke, causes the overwhelming majority of smoking-related diseases.
- ▶ Tobacco is a plant and burning it, like burning any plant material, turns thousands of plant-based compounds into thousands of other compounds, some of which are toxic.
- ▶ The cumulative effect of exposure to these toxicants leads to the onset of smoking-related diseases, so people who smoke more cigarettes a day, over a long period, face a greater risk of developing a smoking-related disease.



<sup>1</sup> Effect of smokeless tobacco (snus) on smoking and public health in Sweden, Foulds J, Ramstrom L, Burke M and Fagerström K, Tobacco Control, 2003.

We will always be transparent about our science. This is central to our approach. We publish details of our scientific research on [www.bat-science.com](http://www.bat-science.com) and the results of studies in peer-reviewed journals. We also contribute to debates around tobacco harm reduction at conferences and in publications. Later this year we will be publishing a science and technology report with details of our R&D programme.

Q



Will there ever be a 'safer' cigarette?

A

"Making cigarettes safer is very challenging. Put simply, the difficulty is that when tobacco is burned it produces toxicants in the smoke – it's these smoke toxicants that cause the most harm. We are working on ways to try to reduce some of the toxicants in the smoke, but the science is incredibly complex and we're still a long way from being able to demonstrate reduced risk for smokers.

"So given these challenges, it makes sense to explore tobacco products that involve no combustion. Snus, a type of low-toxicant smokeless tobacco, is a product that's already out there and proven, through over 100 years of use in Sweden, to be substantially less risky than smoking cigarettes. The problem is that it isn't accepted widely as a product. So the challenge isn't only to develop reduced-risk tobacco products, but to develop ones that more smokers will actually want to use as alternatives.

"Therefore, we are also exploring the development of other innovative tobacco products, such as where the tobacco is gently heated instead of burnt. These products look like cigarettes, but without combustion and consequently exposure to smoke toxicants, they could be less risky for the user."

Q



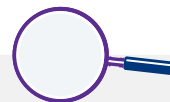
So how important is the science behind harm reduction?

A

"The science is fundamental in better understanding smoking-related diseases and developing innovative products. Only with high-quality science will tobacco companies and regulators be able to properly evaluate the risk profile and harm reduction potential of new product categories.

"It's also vital for consumers to have the assurance that the information they get about new reduced-risk tobacco and nicotine products is based on the best possible science – so they can confidently make an informed choice."

Q



Can scientific research by tobacco companies ever really be credible?

A

"We know that this is contentious. But we also know it's our responsibility to contribute to the science of tobacco harm reduction. And, maybe I'm biased, but with state-of-the-art R&D facilities, an annual R&D spend in excess of £170 million, hundreds of scientists covering many disciplines, and over 100 peer-reviewed papers published, I truly believe we're making a significant and valuable contribution to that science.

"And more and more we're getting recognition externally. Our scientists are regularly invited to present at leading scientific conferences and to contribute to workshops and expert panels, such as for the US Food and Drug Administration."

Q&A

with Dr David O'Reilly  
Group Scientific Director

## The bigger picture

Developing reduced-risk tobacco products will be less impactful if information about the different risk profiles cannot be communicated to consumers so they can make informed choices. To do this there needs to be an agreed science-based regulatory framework for evaluating these products. The challenge is to build a sufficient weight of scientific evidence to base such regulation and consumer information on.

To date, the only regulator to rise to the challenge is the US Food and Drug Administration (FDA), which has authority in the United States to regulate tobacco products, including evaluating submissions on candidate 'modified risk tobacco products'.

In 2012, a funding initiative by the inter-agency partnership between the FDA and the US National Institutes of Health was announced, focusing on finding scientific evidence to support regulation, including the characterisation of modified risk tobacco products. We think this kind of collaboration and inclusive approach is a really positive step and we're working with some of our research partners in submitting applications.

## So, what's next?

To achieve our aim of being able to offer a range of less risky tobacco and nicotine alternatives that consumers actually want to use, we still need to undertake a great deal more research and development – which we're very much committed to for the long term.

In the short term, our Nicoventures business will continue to build a portfolio of next generation nicotine products, including further development of e-cigarettes and the development of other innovative nicotine inhalation products.

“

Through over 30 years' experience in public health, I've come to realise that an abstinence-only approach to tobacco simply isn't enough. Over a billion people today still smoke cigarettes and most do so because they're addicted to nicotine. But let's be clear: it is not the nicotine that kills, it's the smoke. Therefore it is highly significant that smokers are beginning to migrate from combustible cigarettes, the most harmful form of tobacco use, to non-combustible nicotine inhalation devices such as e-cigarettes. This shift has the potential to prevent hundreds of millions of premature deaths and chronic tobacco-related disease. This is the ultimate goal of public health and should be encouraged.

Whatever people think about 'big tobacco', it can't be denied that they understand the needs of smokers and can deliver alternative products at a large scale. BAT and its subsidiaries can play a pivotal role in the innovation of less harmful nicotine products, which are affordable and accessible to adult smokers. Through this public commitment to tobacco harm reduction, the Group makes itself accountable to its consumers and society. This should be applauded and, if successful, BAT could become part of the solution to addressing the epidemic of tobacco-related disease.

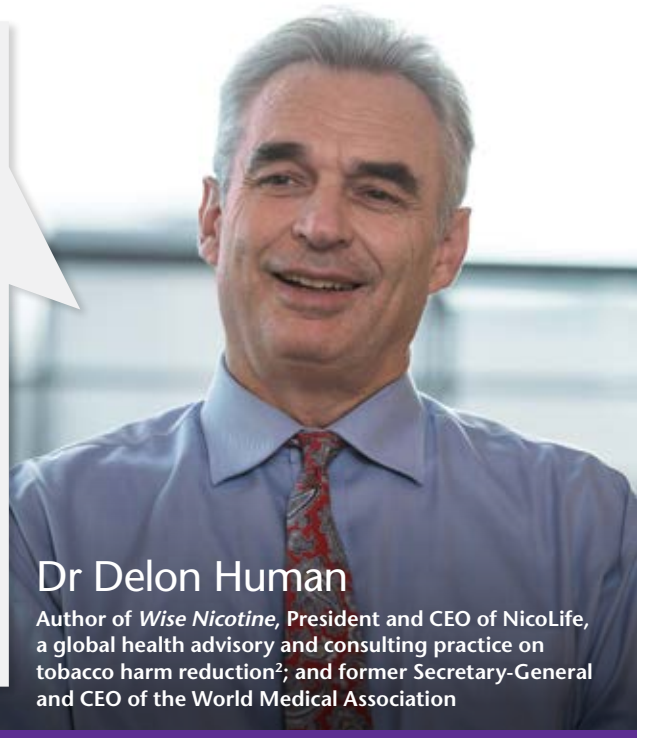
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Applying harm reduction principles to public health policies on tobacco/nicotine is more than simply a rational and humane policy... It has the potential to lead to one of the greatest public health breakthroughs in human history by fundamentally changing the forecast of a billion cigarette-caused deaths this century.

David Sweanor, Adjunct Professor, Faculty of Law, University of Ottawa and a Special Lecturer, Division of Epidemiology and Public Health, University of Nottingham<sup>1</sup>

More collaboration between the tobacco industry, academia and tobacco research centres is also key to establishing an evidence-based regulatory framework to assess new products.

Ultimately, consumers need to be able to make an informed choice about different products based on their risk profile. So, as well as developing new products, we have a role to contribute to the robust science that will help provide them with that information.



**Dr Delon Human**

Author of *Wise Nicotine*, President and CEO of NicoLife, a global health advisory and consulting practice on tobacco harm reduction<sup>2</sup>; and former Secretary-General and CEO of the World Medical Association

<sup>1</sup> *Tobacco harm reduction: How rational public policy could transform a pandemic*, Sweanor D, Alcabes P and Drucker E, International Journal of Drug Policy, 2007.

<sup>2</sup> NicoLife has provided consultancy services to BAT on our approach to harm reduction.



## Dr Richard Tubb

Independent Non-Executive Director, Board of British American Tobacco p.l.c.



Tobacco harm reduction is an area I've long been interested in, especially as I'm a physician and I grew up on a tobacco farm in the US.

In my view, BAT's clear strategic drive and the kind of leading science I've seen at its heart is second to none. And the progress they're making, particularly in the nicotine category, should not be underestimated.

I think the tobacco industry is entering a whole new phase of its history and I'm very excited to be part of it.

## Get in touch

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Ernst & Young LLP has been engaged by British American Tobacco to provide limited external assurance of this focus report. A full assurance statement, including the scope of work and conclusions, can be found at [www.bat.com/assurance](http://www.bat.com/assurance).



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